MAR 2 2 2007

K070485

Section II.
510(k) Summary

GENERAL INFORMATION

Manufacturer: Cardiva Medical, Inc.
2585 Leghorn Street
Mountain View, CA 94043
Phone: 650-964-8900
Facsimile: 650-964-8911
Establishment Registration Number: 3004182619
(Glenn Foy, President)

Contact Person: Michael J. Billig
Regulatory Consultant
Experien Group
Phone: 408-400-0856
Facsimile: 408-400-0865

Date Prepared: February 16, 2007

DEVICE INFORMATION

Trade Name: Cardiva Medical Boomerang™ PlusWire System

Classification Names: Vascular Clamp (21 CFR §870.4450)

Classification: Class II

PREDICATE DEVICES

Cardiva Medical Boomerang™ Wire System (K051817)

INTENDED USE/INDICATIONS FOR USE

The Boomerang™ Wire/PlusWire System is intended to promote hemostasis at arteriotomy sites as an adjunct to manual compression. The Boomerang™ Wire/PlusWire System is indicated for use in patients undergoing diagnostic and/or interventional femoral artery catheterization procedures using 5F, 6F or 7F introducer sheaths.

DEVICE DESCRIPTION

The Boomerang™ PlusWire System is an extension of the Boomerang Wire System family of devices. The Boomerang PlusWire System is intended to promote hemostasis at arteriotomy sites as an adjunct to manual compression. The Boomerang™ PlusWire System includes design modifications to enhance ease of device removal and to minimize ooze from the tissue tract. The Boomerang PlusWire System maintains the same indication for use as the Boomerang Wire System family of devices.

The Boomerang PlusWire System consists of a sterile disposable Boomerang PlusWire and a sterile disposable Boomerang Clip. In conjunction with manual compression, the Boomerang PlusWire System provides temporary hemostasis at a femoral access site after femoral arterial catheterization while allowing continued distal perfusion. After completion of catheterization, the Boomerang PlusWire is inserted into the artery through the existing introducer sheath. After insertion, the distal tip of the Boomerang PlusWire is deployed, which opens the flat, low-profile Boomerang Disc within the lumen of the femoral artery. The Boomerang Disc is then pulled back gently to the distal end of the introducer sheath. The introducer sheath is then removed from the vessel over the Boomerang PlusWire and the low-profile Boomerang Disc conforms to the contours of the vessel and secures it against the intima, sealing the arteriotomy. As gentle tension is applied to the Boomerang PlusWire, the sleeve covering the tensioning coil is gently retracted until the distal tip appears at the skin surface to expose the coated tensioning coil to the tissue tract. The applied tension is maintained by the external Boomerang Clip at the surface of the skin at the puncture site. The tension between the Boomerang Disc and the Boomerang Clip creates a site-specific compression of the arteriotomy and tract and establishes temporary hemostasis. This allows natural recoil of the smooth muscle of the vessel wall to occur at the arteriotomy site while the body's natural clotting process begins. Following the procedure, the Boomerang Disc is collapsed and the Boomerang PlusWire is completely removed from the artery. No part of the device is left behind. Final closure of the arteriotomy occurs by applying gentle manual or mechanical compression after removal of the Boomerang PlusWire System.

SUBSTANTIAL EQUIVALENCE

The Boomerang PlusWire System is substantially equivalent to the predicate device with regard to function, intended use, physical characteristics and performance testing.

PERFORMANCE TESTING

Various testing which included bench, biocompatibility, animal and clinical testing was performed on the Boomerang PlusWire System to insure the product and the product materials were adequately tested and evaluated to demonstrate the product meets or exceeds the performance requirements and is safe and effective for its intended use.

CONCLUSION

The Boomerang PlusWire System was properly designed, tested and shown to be substantially equivalent to the identified predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 7 2007

Michael J. Billig
Regulatory Consultant for Cardiva Medical
Experien Group, LLC
155-A Moffett Park Drive
Suite A-101
Sunnyvale, CA 94098

Re: K070485
Trade/Device Name: Cardiva Medical Boomerang PlusWire System
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: II (two)
Product Code: DXC
Dated: February 16, 2007
Received: February 20, 2007

Dear Mr. Billig:

This letter corrects our substantially equivalent letter of March 22, 2007. We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In

addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Section I.
Statement of Indications for Use

Statement of Indications for Use

510(k) Number (if known): K070485

Device Name: Cardiva Medical Boomerang™ PlusWire System

Indications for Use:

The Boomerang™ Wire/PlusWire System is intended to promote hemostasis at arteriotomy sites as an adjunct to manual compression. The Boomerang™ Wire/PlusWire System is indicated for use in patients undergoing diagnostic and/or interventional femoral artery catheterization procedures using 5F, 6F or 7F introducer sheaths.

Please Do Not Write Below This Line – Continue On Another Page If Needed

Concurrence of ~~CDRH, Office of Device Evaluation (ODE)~~ Donna R. Vachney
(Division Sign-Off)
Division of Cardiovascular Devices

Prescription Use X or Over-the-counter Use _____